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THIN FILM PERIPHERAL NERVE ELECTRODE

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by

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1.0 BACKGROUND

A program to develop a functional neuromuscular system (FNS) capable of graded and stable activation of hand muscles for the restoration of grasp in quadriplegic individuals is being undertaken. The objective of the program is the development of a thin film nerve cuff electrode and the demonstration of the efficacy of the electrode for grasp in an *in vivo* study using a raccoon model. The cuff electrodes are fabricated by vacuum depositing metal films on thin sheets of FEP Teflon and photolithographically patterning the leads and charge injection sites. The patterned substrate is then thermally sealed with a second polymer layer to electronically isolate the leads from the physiological environment. Once all planar fabrication processes, i.e., photolithography, vacuum deposition, and etching have been completed, the electrode is cut out of the substrate and the desired cuff and lead geometries created by thermoforming.

An example of an electrode in planar geometry prior to thermoforming the cuff is shown in Fig. 1. The leads and charge injection sites are patterned on a large polymer substrate with the leads extending to a bonding pad located several centimeters from the cuff. Four charge injection sites, designed to evaluate anodal steering, are shown on the cuff.

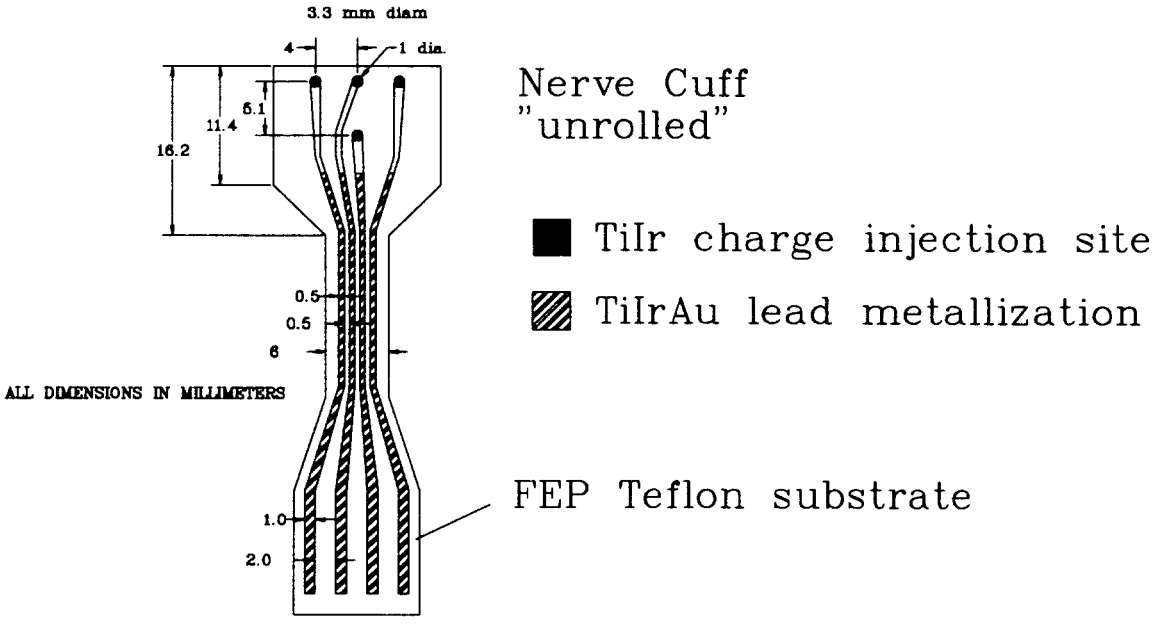

Figure 1. A thermoformable nerve cuff having four charge injection sites in a geometry suitable for evaluating anodal steering.

2.0 TECHNICAL PROGRESS

The contract is now operating under a no-cost-extension at a relatively low level of effort. During this period, chronic studies of nerve cuffs implanted on the median and ulnar nerves of three raccoons are being completed. In this report, the results of the first chronic implantation and the subsequent redesign of the electrodes are described.

A nerve cuff with the design shown in Fig. 2 was implanted for 6 weeks in the upper arm of a raccoon. Both branches of the median nerve and the ulnar nerve were placed inside the cuff. The fabrication of the cuff and the initial functional responses were described in Report No. 6.

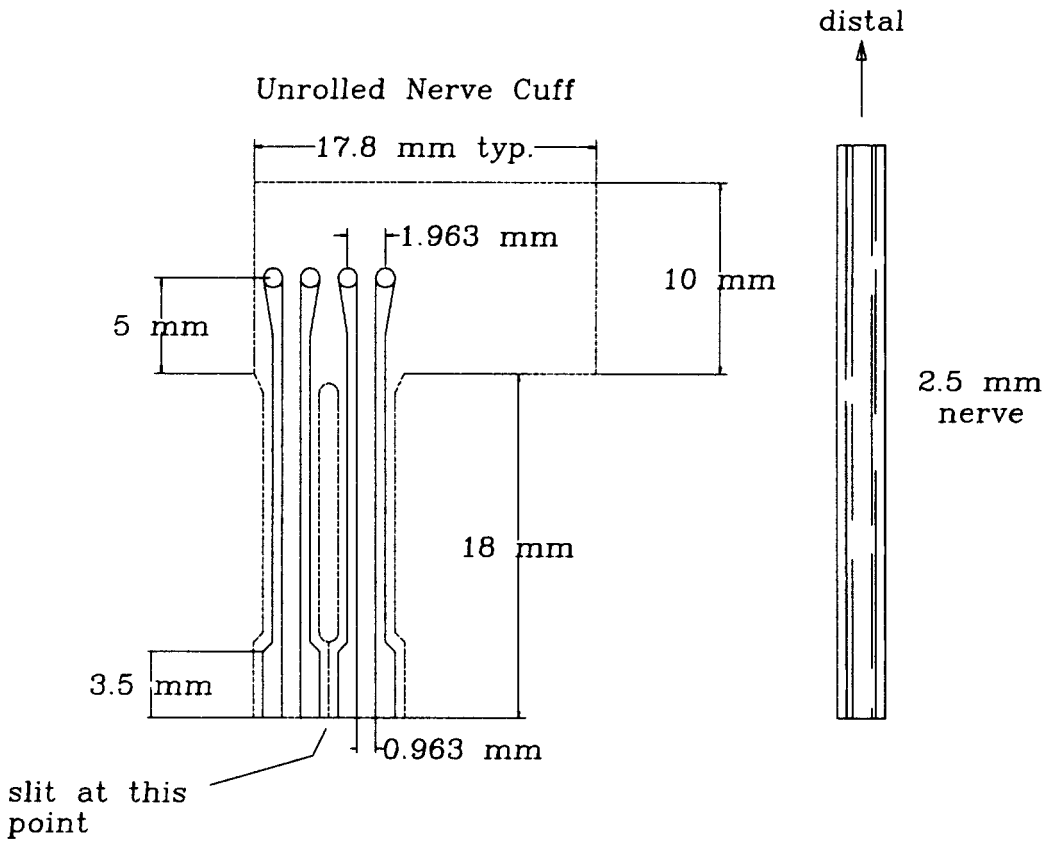

Figure 2. Layout of first chronic nerve cuff with four 1 mm diameter Ir charge injection sites in a circumneural pattern.

After the 6 week implantation period, the functional response was reevaluated. There was no response to prior maximal current pulses at any of the four charge injection sites. Examination of the implantation site revealed that the cuff had come off the nerve. Several other serious problems were observed:

- there was no metallization on the FEP Teflon substrate and no remnants were noticed in the tissue surrounding the implantation site;
- the inner silastic insulation delaminated from the Teflon;
- the leads were pulled out of the conductive epoxy at the bonding pads.

The loss of metallization was surprising since TiIr films in previous chronic implants on the cat sciatic nerve survived without apparent degradation. The films are quite robust and, at least in the as-fabricated condition, pass a tape pull test. Since there was no stimulation during the implantation period, the metallization could not have actively corroded. We hypothesize that the metallization delaminated from the Teflon and was overlooked during explantation. Adhesion of the silastic inner insulation to the FEP Teflon has always been a concern. During fabrication of the failed cuff a H_2O activated adhesion primer was applied to the Teflon before spinning on the silastic. It is possible that poor adhesion resulted from inadequate curing of the primer. The manufacturer recommends a cure time of 1 hour in air with a 50% relative humidity. The cuff was fabricated when the humidity level in the laboratory was seasonally low, about 10%, and the 1 hour cure time may have been insufficient to complete the cure process. Failure at the lead-epoxy junction may have been caused by excessive force during explantation. The epoxy remained adherent to the metallization at the bonding pads and the metallization under the epoxy was also adherent to the Teflon.

Based on the poor performance of this electrode, modifications to the design and fabrication procedure were made. Figure 3 shows the layout of a third cuff electrode that will be used for the final set of chronic studies. A significant difference between this and previous designs is the absence of a relatively long tab that separates the bonding pads from the cuff portion of the electrode. Lead wires will now be epoxied to the bonding pads in close proximity to the nerve. This geometry has been adopted to reduce mechanical interaction between the cuff and the nerve and to simplify implantation. An additional improvement is the small tab that will be used as a

strain relief for the lead wires. In the new design, the lead wires next to their termination at the cuff are threaded through a 1 cm length of silastic tubing. This tubing is then bonded to the tab with silicone adhesive and additional adhesive forced inside the tubing to anchor the wires. The lead wires are multistrand Teflon-coated stainless steel.

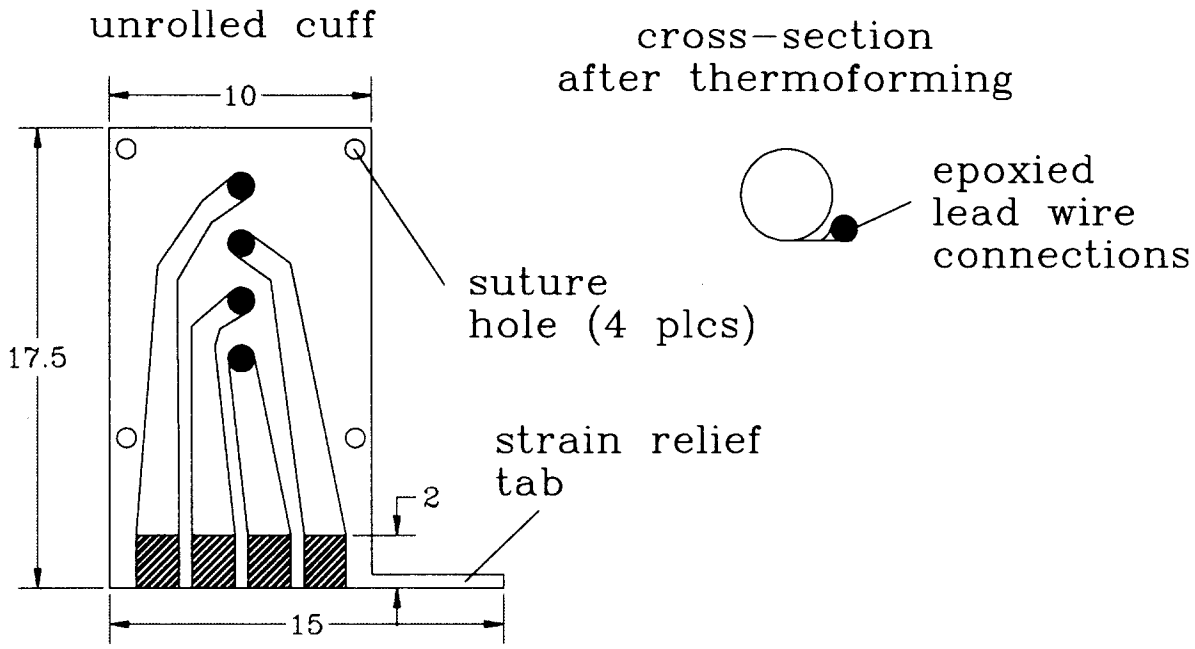

Figure 3. Layout of the redesigned nerve electrode. The electrode employs four 1 mm diameter charge injection sites in a circumneural geometry (dimensions in millimeters).

Small holes, formed with a 20 gauge hypodermic needle, were made near the corners of the uncurled cuff. Sutures can be placed through the holes to facilitate opening and closing of the cuff during implantation and can also be used to "lock" the cuff around the nerve. The location of the holes on the cuff circumference is chosen so that they overlap when the cuff is curled to the anticipated diameter of the nerve. The suturing is loose to allow some expansion of the cuff to accommodate postoperative edema.

The reason for poor adhesion of the metallization in the first chronic implant is unknown. A review of the processing conditions revealed that the erosion zone on the Ti sputter target was

heavily grooved and the target near end-of-life. As the erosion zone deepens, the current-voltage characteristics of the sputtering process change and some variation in film properties might be expected. A new Ti target was purchased and used in the fabrication of the latest cuffs.

3.0 FUTURE WORK

Three of the redesigned electrodes will be implanted in three animals for six weeks. The electrode evaluation will involve initial and final measurements of functional response and histology of the nerves at the implantation site.